

REMARKS

Claims 1-12 and 14-38 are pending in this application. Applicant notes that the present Office Action states that the rejections are both final and non final. Applicant called Examiner Mehta on November 12, 2008, and Examiner confirmed that the present rejections are non-final. Applicant respectfully requests favorable reconsideration and allowance in light of the remarks contained herein.

Applicant's Record Under M.P.E.P. § 713.04 of Interview with the Examiner

Applicant's attorney appreciates the Examiner's time and consideration in conducting the telephone interview of January 22, 2009. Applicant respectfully submits the following record of the telephone interview under M.P.E.P. § 713.04.

The following persons participated in the interview: Examiner Parikha Mehta, and Applicant's Attorney Nathan Rees (reg# 63,820). The claims were discussed with reference made to the cited art. Applicant directed Examiner to various claimed features which Applicant believes are not taught by the cited art. Examiner indicated that portions of the claims were believed to recite intended uses. While Applicant disagreed with this assessment, Applicant submitted that a minor claim change to address Examiner's concerns could be made without effecting the scope of the claims.

The present rejection under 35 U.S.C. §112 was discussed and Examiner provided ideas on overcoming these rejections. While Applicant also disagreed with Examiner's assessment of the rejection, Applicant submitted that minor claim changes could also be made in this instance to address Examiner's concerns without effecting the scope of the claims.

Applicant appreciates Examiner's input on the modifications discussed above. In view of the telephone interview of January 22, 2009, Applicant hereby presents the following for the Examiner's consideration.

Claim Amendments

Claim 1 has been amended to recite “a bracket configured to attach a first medical device support of said plurality of medical device supports, to the body of an imaging probe; and a latch within said first medical device support configured to hold a medical device at a predetermined angle....” Applicant has amended claim 1 to clarify the claim in light of what Examiner asserts as an antecedent basis and intended use issue. Claim 4 has also been amended to be consistent with the amendments of claim 1. No change in claim scope is intended. As such, no new matter has been added.

Claims 9 and 35 has been amended to recite the words “configured to” instead of using the word “for.” Applicant has amended these claims to clarify the claims in light of what Examiner asserts and intended use issue. No change in claim scope is intended. As such, no new matter has been added.

Claim 16 has been amended to recite “said clamping controlled at least in part by a slidably coupled latch having a dimension keyed to a diameter of said medical device, wherein said slidably coupled latch comprises an upper surface and a lower surface, said lower surface including a wedge portion which tapers upward to define said dimension.” Applicant has amended this claim to clarify the claim in light of what Examiner asserts as an asserted antecedent basis issue. Further, claim 16 has been amended to clarify one aspect which Applicant regards as an embodiment of the present invention. Support for this amendment is found throughout the specification, figures, and claims as filed (*see e.g.* Figure 10C). As such, no new matter has been added.

Claims 18 and 30 have been amended to recite “said guide is configured to define a closing angle with respect to said proximal end of said probe....” And claims 19 and 31 have been amended to recite “said closing angle corresponds to a target depth of said positioned medical device below said surface of said object....” Applicant has amended these claims clarify the claims in light of what Examiner asserts as an intended use issue, and to overcome the present rejection under 35 U.S.C. §112. No change in claim scope is intended. As such, no new matter has been added.

Specification Amendments

The Office Action has objected to the title of the invention as not descriptive. While Applicant does not agree that the title is improper, Applicant has amended the title as shown above in order to advance prosecution.

Claim Objections

Claims 1, 4, and 16 were objected to as containing terms with unclear antecedent basis. While Applicant believes the previously presented claims were proper, claims 1, 4, and 16 have been amended recite “first medical device support” in order to clarify the claim language. No change in claim scope is intended by these amendments. Applicant submits that the objections are overcome and respectfully requests that the objections be withdrawn.

Claim 8 is objected to because Examiner asserts that the claim language fails to further limit the structure of the claimed invention. More specifically, Examiner asserts that claim 8 sets forth limitations for the medical device, which is not positively set forth as part of the inventive apparatus. Applicant agrees that the medical device is not part of the apparatus claimed in claim 1. However claim 1, as amended, recites “a latch within said support configured to hold a medical device....” As such, the limitations of claim 8, which recite types of medical devices, clearly limits the structure of the latch as the latch must be configured to releasably hold such various devices. Thus, Applicant submits that claim 8 properly limits the structure of the claimed invention and respectfully requests that the objection be withdrawn.

Rejection Under 35 U.S.C. § 112

Claims 18, 19, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As stated above in the interview summary, Applicant disagrees with Examiner’s assertion that these claims are not enabled. Explanation of these claims can be found throughout the specification, drawings, and original claims as filed (*e.g.* paragraphs [0024-0025, 0031]; Figures 9-11). Regardless, as stated above, it was indicated that minor amendments could clarify the claim language and overcome the present rejection. Accordingly, claims 18 and 30, and claims 19 and 31, are presently amended to

recite “said guide is configured to define a closing angle” and “said closing angle corresponds to a target depth” respectively. Applicant submits that no scope change is intended. As such, the amendments find support in at least the above cited portions of the present Application. Therefore, Applicant respectfully requests withdrawal of the present rejection.

Rejection Under 35 U.S.C. § 102

Claims 16-27 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,296,614 as to Pruter (hereinafter “Pruter”). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference,” *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Because the Pruter reference fails to teach each and every claim element in the present application, Applicant respectfully requests withdrawal of the present rejection.

Claim 16, as amended, recites “said clamping controlled at least in part by a slidably coupled latch having a dimension keyed to a diameter of said medical device, wherein said slidably coupled latch comprises an upper surface and a lower surface, said lower surface including a wedge portion which tapers upward to define said dimension.” Pruter fails to teach these limitations at least because (i) Pruter does not teach a slidably coupled latch; and (ii) Pruter does not teach a latch having the recited wedge portion configured to create the specified dimension when coupled. As clearly shown in figure 4 of Pruter, lever 36 which secures a needle is pivoted and held shut by a spring force from item 28. *See also* Col. 4 lines 53-57. In fact, Pruter explicitly names item 36 “lever” which, by definition, requires it to be configured to pivot at a fulcrum point.¹ Therefore, it is clear that nothing in Pruter may be defined as a slidably coupled latch.

It is noted that in the “response to arguments” section of the present Office Action Examiner attempts to define the “slide” of the present claims as the sliding surface in which a medical device, such as a needle, will travel along for injection into a target. Office Action at 7. This interpretation, however, does not make logical sense in light of the context of the

¹ The term “lever” is defined as follows: A rigid piece which is capable of turning about one point, or axis (the fulcrum), and in which are two or more other points where forces are applied; -- used for transmitting and modifying force and motion. *Webster's Revised Unabridged Dictionary*. Alternatively: A simple machine consisting of a rigid bar pivoted on a fixed point and used to transmit force, as in raising or moving a weight at one end by pushing down on the other. *American Heritage Dictionary, Fourth Edition*.

claim language. For example, in claim 16 the slidably coupled latch assists in clamping the medical device and in defining the dimension in which the device will slide, whereas Examiner is attempting to define the actual sliding of the medical device within the dimension created by the slidably coupled latch as meeting this limitation. Clearly, Examiner's interpretation cannot hold when viewed in light of the requirements of the claim. Hence, Applicant requests that the rejection be withdrawn.

Further, there is no wedge portion on clamp 36 of Pruter which could be interpreted as teaching a "slidably coupled latch comprises an upper surface and a lower surface, said lower surface including a wedge portion which tapers upward to define said dimension" as set forth in currently amended claim 16. As such, Applicant respectfully requests withdrawal of the present rejection.

Claim 24 recites "a channel configured to accept the longitudinal axis of an elongated medical device" and "a slide configured to traverse said channel, said slide applying controlled clamping force on an accepted elongated medical device." Examiner makes the same logical flaw in reading this limitation as noted above. In other words, the claim requires that a slide which traverses a channel provides clamping force on an accepted medical device, whereas Examiner's rejection attempts to cite the sliding of the medical device as teaching this limitation. The context of the claim clearly prevents Examiner's interpretation. Logically, a medical device sliding cannot be considered a slide applying a controlled clamping force on the medical device. Thus, Applicant requests withdrawal of the present rejection.

Claim 35 recites "releasably attaching a needle to said attached needle guide by sliding a clamping mechanism within said selected one of said needle guides so that the longitudinal axis of said needle lies along a longitudinal axis of said selected one of said needle guides, said needle having said particular gauge." Nothing in Pruter teaches releasably attaching a needle to a guide by *sliding* a clamping mechanism within the guide (*see* arguments above for claim 16). As a result, Applicant requests that the rejection be withdrawn.

Claim 35 further recites "positioning a guide support bracket at said proximal end of said probe, said guide support bracket configured to accept, one at a time, a plurality of

needle guides each having either a different angle of attack or accepting a different gauge needle,” “selecting a needle guide having a particular angle of attack with respect to said proximal end of said probe, said selected needle guide accepting a particular gauge” and “releasably attaching said selected needle guide to said attached bracket.” In Examiner’s rejection of claim 1, Examiner admits that Pruter does not teach “multiple device supports having different attack angles.” Office Action at 5. For at least that reason, Pruter clearly fails to teach the above limitations.

While the present rejection of claim 35 is under 35 U.S.C. §102, and Examiner has not relied on Hayakawa (U.S. Patent No. 5,967,985, hereinafter “Hayakawa”) as remedying the above shown deficiency, Applicant notes that the Hayakawa reference does not serve to remedy the deficiency. Examiner asserts that Hayakawa “teaches that it is helpful to have multiple guides of differing attack angle in order to more accurately position a needle with respect to the depth of the target within the patient.” Office Action at 5. However, Hayakawa is discussing attaching different ones of an entire guide member to a “main frame” which is defined as the main frame structure of the actual ultrasound device. *See* Col. 3 line 66; Col 5 lines 32-37. The reference further discusses sensors on the main frame of the ultrasound device which detect the presence of a guide member. *Id.* at Col 5 lines 19-31. This structure and functionality is clearly different than the claimed invention which (i) positions a guide support bracket on the probe, where (ii) the guide support bracket is configured to accept and attach various selected needle guides. In other words, a user of the claimed invention would not be required to continually attach or detach the entire guide from the “main frame” as is taught by Hayakawa in order to select a different angle of attack. Therefore, a combination using the Hayakawa reference also fails to teach limitations of claim 35.

Claims 17-23, 25-27, and 36-37 depend either directly or indirectly from independent claims 16, 24, or 35, and thus inherit each and every limitation of their corresponding independent claim. As a result, claims 17-23, 25-27, and 36-37 are allowable for at least the reasons set forth above. Further, dependent claims 17-23, 25-27, and 36-37 contain limitations that are patentable in their own right.

Rejection Under 35 U.S.C. § 103

Claims 1-12 and 14, 15, 28-34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruter, in view of Hayakawa. The Federal Circuit has stated that when determining whether a claim is obvious, an examiner must make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Because the proposed combination fails to teach one or more limitations of the claims, Applicant respectfully submits that the present rejections are improper.

Claim 1 recites “a plurality of medical device supports, one or more of said plurality of medical device supports being configured to create a different angle of attack than another of said plurality of medical device supports” and “a bracket configured to attach a first medical device support of said plurality of medical device supports, to the body of an imaging probe.” In the previous response it was noted by Applicant that in Pruter, bracket 6 has edges 52 and 54 which have different lengths that function to create and fix the angle of attack of any device placed within the support pieces. *See* Pruter col. 3 lines 36-41, figure 2. However, there is no teaching of differing supports which create different angles of attack. Examiner appears to agree with this analysis as the present action states that “Pruter does not teach the inclusion of multiple device supports having different attack angles.” Office action at 5. Applicant further notes that inherent in the above design of Pruter is the need to change the entire bracket 6 if a different angle of attack is desired by a user.

Examiner relies on the teachings of Hayakawa as explained above with respect to the argument of claim 35 for teaching the use of “multiple guides of differing attack angles.” However, as also shown, a user of Hayakawa is required to change the entire guide structure which is to be attached to the “main frame” of the probe in the event that a new angle is desired. This is in contrast to the limitations of claim 1 that provide for a guide comprising a bracket, which is configured to attach a separate medical device support of the plurality of medical device supports configured to create a different angle of attack. Therefore, the

proposed combination fails to teach every limitation of claim 1. Accordingly, Applicant respectfully requests withdrawal of the present rejection.

Claim 9 recites “said latch configured to be fitted over said rod where said rod is seated in said seating area, said latch comprising a tapered wedge portion configured to be positioned below a seated rod.” It is noted that nothing in Pruter can be characterized as a latch which fits over a rod and has a tapered wedge portion to be positioned below the rod. The Office Action states that, in Pruter, a latch with overhang 92 is placed over a needle. The Office action further relies on a triangular groove of this same overhang portion (which the Office action holds as being positioned “over” a rod), as teaching a wedge portion configured to be positioned below a seated rod. Office Action at 5-6. Clearly, the same structure of Pruter cannot be said to teach something that is configured to be placed both over and below a seated rod. Hence, nothing in that portion, or any other portion of Pruter, teaches a tapered wedge for positioning below a rod.

The Office Action states that portions of these limitations were not given patentable weight. Office Action at 6. This was due to the fact that the Examiner refused to consider functional language. While Applicant believes that this action by Examiner is improper, claim 9 has been amended to avoid Examiner’s reading. Thus, Applicant respectfully requests that the rejection be withdrawn.

Claim 28 recites “releasably connecting a bracket to the proximal end of said probe” and “releasably connecting a guide to a connected bracket, so that the longitudinal axis of said guide falls along the longitudinal axis of said probe, said guide being selected from a plurality of guides which are adapted to form different angles of attack for said medical device.” As noted above with respect to claims 1 and 35, the proposed combination of Pruter and Hayakawa fail to teach a device which is able to releasably connect a guide to a bracket in order to change an angle of attack. Therefore, the proposed combination does not teach releasably connecting a bracket to a probe and releasably connecting a guide to a connected bracket, where the guide is selected from a plurality of guides which provide different angles of attack. Hence, Applicant requests that the rejection of claim 28 be withdrawn.

Claims 2-8, 10-12 and 14, 15, 29-34 and 38 depend either directly or indirectly from independent claims 1, 9, 16, 24, 28, or 35, and thus inherit each and every limitation of their

corresponding independent claim. As a result, claims 17-23, 25-27, and 36-37 are allowable for at least the reasons set forth above. Further, dependent claims 2-8, 10-12 and 14, 15, 29-34 and 38 contain limitations that are patentable in their own right. For example, claim 10 recites “wherein said latch is positioned perpendicular to said seating area and wherein said latch slides across said seating area.” This limitation is not addressed by the present action. Further, nothing in the cited art appears to teach a latch that is positioned perpendicular to said seating area and wherein said latch slides across said seating area.

Additionally, claim 32 recites “wherein said releasably clamping is controlled at least in part by a slide operating transverse to said longitudinal axis.” This limitation is also not addressed by the present action. Clearly, nothing in the proposed combination teaches a slide which operates transverse to the longitudinal axis of a medical device in order to clamp the device. Accordingly, Applicant requests that the present rejection be withdrawn.

Claim 33 depends on 32 and further recites “wherein at least a portion of said slide contains a ramp.” The Office Action does not specifically address this limitation, which even was, at one point, considered allowable subject matter. In the event that Examiner persists in this rejection, it is respectfully requested that Examiner specifically indicate what portions of the art are believed to teach the slide operating transverse to said longitudinal axis recited in claim 32, which further contains the ramp of claim required by claim 33. Otherwise, Applicant respectfully requests withdrawal of the present rejection.

Claim 38 recites “removing said needle guide from a plurality of needle guides of like gauge but having different angles of attacks, said plurality of needle guides being held by a common bond.” Examiner attempts to distort this claim language so as to read the “common bond” as being an ultrasound device. Applicant respectfully submits that this reading is not reasonable interpretation in light of the specification. Further, the claim requires that the needle guide is removed from a plurality of guides. Therefore the plurality of guides are connected to the common bond simultaneously. Thus, the ultrasound device of Hayakawa cannot serve as a “common bond” as it is not possible to have multiple guides attached. Thus, Applicant requests withdrawal of the present rejection.

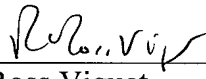
Conclusion

In view of the above, Applicant believes the pending application is in condition for allowance and respectfully requests favorable reconsideration.

Applicant believes no fee is due with this response. However, if any additional fee is due, or at any time during the pendency of this application, please charge any additional fees required or credit any overpayment to Deposit Account No. 06-2380, under Order No. 65744/P016US/10316060 from which the undersigned is authorized to draw during the pendency of this Application pursuant to 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees.

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Respectfully submitted,

By  _____

R. Ross Viguet

Registration No.: 42,203

FULBRIGHT & JAWORSKI L.L.P.

2200 Ross Avenue, Suite 2800

Dallas, Texas 75201-2784

(214) 855-8000

(214) 855-8200 (Fax)

Attorney for Applicant